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09/423,042	01/19/2000	BRUNO GUY	06132/054001	6264
21559	7590	02/20/2007	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			PORTNER, VIRGINIA ALLEN	
			ART UNIT	PAPER NUMBER
			1645	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/423,042

Applicant(s)

GUY ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-9, 11, 14, 15, 18, 25, 37-40 and 42-47 is/are pending in the application.
- 4a) Of the above claim(s) 11, 43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-9, 14, 15, 18, 25, 37-40 and 42, 45-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 5-9, 11, 14-15, 18, 25, 37-40, 42-47 are pending. Claims 11 and 43-44 depend from canceled claims.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 8, 2003 has been entered.

Election/Restrictions

1. Newly submitted claims 11 and 43-44 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims depend from canceled claims and the combination of limitations that they are intended to recite is unclear, and therefore are considered to be directed to a non-elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 11 and 43-44 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Objections/Rejections Withdrawn

2. All rejections of claims under 35 USC 112, second are herein withdrawn in light of Applicant's amendments and traversal.
3. The prior art rejections under 35 USC 102(b) by Lee et al (1995) and Laszlo et al (1992) are herein withdrawn in light of Applicant's traversal and reconsideration of the claim limitations recited.

Rejections Maintained/Response to Arguments

4. Claims 5-9, 14-15, 18, 25, 37-40, 42, 45-47 rejected under 35 U.S.C. 112, first paragraph (scope of enablement and written description) are addressed together and traversed by stating that "the claims have been amended to specify that which the Examiner has deemed to be enabled: the use of prophylactically effective *H. pylori* polypeptide antigens in methods of inducing a prophylactic immune response, using the specific regimens and routes specified in the claims."
5. It is the position of the examiner claims 5-9, 14-15 and 18 no longer recite DNA and peptides and therefore are not longer rejected under 35 USC 112, first paragraph (scope of enablement), but claims 25, 37-40, 42, 45-47 still recite the terms peptide and DNA molecule (see claim 42) and independent claim 25 recites the term "antigen" which is defined in the specification. Therefore, the scope of enablement is still maintained for reasons of record over independent claim 25 and all claims dependent therefrom. The lack of written description is also partially obviated for claim 5 and all dependent claims therefore, but is herein maintain over claim 25 and dependent claims therefore, for reasons of record, and in light of the fact that Applicant's traversal is not commensurate in scope with the instant claimed invention.

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6. Claims 5-6, 12, 14-15, 18, 25, 37, 39-40, 42 and 47 rejected under 35 U.S.C. 102(b) as being anticipated by WO96/31235 in light of the English version US Patent No 6,126,938, is traversed on the grounds that the claims require the administration to be by the subdiaphragmatic, systemic route, thus excluding the administration of antigen to the dorsolumbar region which is now excluded from the claims. Additionally, the methods steps of administering by a mucosal route followed by a parenteral route is required by claim 25 and all dependent claims.

7. It is the position of the examiner that Applicant claims the administration of the *Helicobacter pylori* polypeptide to the dorsolumbar region (pending claim 18, depends from claim 5) and therefore has not excluded this embodiment from the scope of the claims and actually has included this embodiment within the scope of what is now claimed.

8. With respect to the recitation of the phrase "comprising in order the steps of:" mucosally administering... then parenterally administering, it is the position of the examiner that WO96/31235 discloses carrying out these steps more than one time (see English translation US Pat. 6,126,938, col. 7, lines 1-2), wherein the method would comprise mucosal followed by parenteral, even if an additional step of parenteral was carried out before the mucosal step (see instant claims 37 and 38). Clearly the WO96/31235 document discloses a method that comprises repeat repeating the parenteral administration (first agent) followed by the second agent **(mucosal) repeated first agent (parenteral) repeated second agent (mucosal)**. Therefore the method of WO96/32135 does disclose the method step of mucosal followed by parenteral in that order.

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9. With respect to oral administration, WO96' English translation, states that the mucosal immune response can be obtained by the oral route (see '938, col. 2, line 36; col. 6, line 21 "oral route" and '938, claim 6). The instantly claimed method has not been distinguished from the method of Guy et al that repeats the administration of the parenteral/mucosal/parenteral/mucosal and therefore comprises a method that is mucosal before parenteral.

10. Guy et al discloses a method that administers the *Helicobacter pylori* polypeptides by the vaginal or rectal route (see '938, col. 6, line 27) which is a subdiaphragmatic, systemic route, as well as administers the *Helicobacter pylori* polypeptide by systemic injection at the dorsolumbar region by intramuscular injection (instant claim 18). The reference still anticipates the instantly claimed invention as now claimed. Prior responses are incorporated herein by reference.

New Grounds of Rejection

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 5-9, 14-15, 25, 39-40, 42, 45-47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,126,938 (common inventor Bruno Guy). Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed methods are directed to a species of the instantly claimed genus of methods that administer by the sub-diaphragmatic, systemic route, and the allowed method claims include the methods step of urogenital administration (see allowed claim 5) or intragastric administration (see allowed claim 9) and the first product is formulated and parenterally administered, by subcutaneous, intradermal or intramuscular administration and the location of the parenteral administration is (see allowed claims 27-28) defined to include dorsolumbar region for injection (see US Pat. 6,126,938, col. 5, lines 8-17). The allowed species anticipates the instantly claimed genus of methods as now claimed.

13. Additionally, US Pat. 6,126,938, also discloses a method that comprises the steps of mucosally administering a *Helicobacter pylori* antigen (see allowed claims 10-11), which is by an oral or intragastric mucosal route (see allowed claims 15 and 18), and parenterally administering *Helicobacter pylori* antigen (see allowed claims 7-8, and 27-28 and col. 8, line 19). The antigens are encoded by a DNA in an expression cassette (see allowed claims 3 and 26) and are in association with a non-toxic adjuvant, the adjuvant being defined to a "lipid mixture of cholesterol, dipalmitoylphosphatidyl-choline (see allowed claim 20 and col. 11, lines 54-58). This allowed species of invention anticipates the instantly claimed genus of methods that

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comprise first and second steps of mucosally and parenterally administering *Helicobacter pylori* antigen to a mammal.

14. Claim 5-8 and 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,576,244 (common inventors with instant Application: Weltzin and Bruno Guy) . Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed claims are directed to a species within the instantly claimed genus of methods that administer a prophylactic *Helicobacter pylori* polypeptide to a mammal, wherein the allowed claims administer a *Helicobacter pylori* polypeptide together with an adjuvant that is admixture of one or more of LT and LTB (see '244, col. 7, lines 9-19) and deliver the composition by a subcutaneous (allowed claim 5) or intradermal route(allowed claim 6), the subcutaneous route being defined to be the lower back (see col. 9, lines 8-14) and the intradermal route being defined to include skin of the back (see '244, col. 9, lines 14-19). The allowed species anticipates the instantly claimed genus of methods as now claimed.

15. Claim 5 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, (UreA and UreB are defined to be *Helicobacter pylori* antigens (see Spec. col. 11, lines 62-63), 13 (mucosal: defined to include anal, vaginal and intragstric , col. 14, lines 19-20), 15 (Intragastrically) and 18 (prophylactic) of U.S. Patent No. 6,379,675. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed method is directed to a species within the instantly claimed genus of methods that administer any *Helicobacter pylori*

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antigen by a sub-diaphragmatic, systemic route, wherein the method of US 6,379,675, is able to induce strong circulatory immune responses of IgG and IgA in the serum (see col. 13, lines 25-26); the allowed species anticipates the instantly claimed genus.

16. Claim 25, 37-40, 42, 46 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-15 of U.S. Patent No. 6,585,975. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed method comprises the steps of mucosally administering (claim 1 and col. 7, lines 45-51) a *Helicobacter pylori* antigen expressed by a *Salmonella* vector (all claims and col. 5, lines 21-45) and then parenterally administering a *Helicobacter pylori* antigen with alum (all claims, specifically claims 7-8 and col. 5, lines 21-45, col. 7, lines 49-51 defined to be urease or urease subunit of *Helicobacter pylori* claim 3 and col. 10, line 5); the allowed species anticipates the instantly claimed invention as now claimed.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

18. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (1993) in light of Applicant's definition of an *Helicobacter pylori* antigen at page 11 which includes polypeptides that are similar to a *Helicobacter pylori* polypeptide antigen and is able to induce an immune response against *Helicobacter* (see page 11, lines 19-23).

19. Chen et al disclose the instantly claimed invention directed to a method that consists essentially of the step of :

20. Administering to a mammal a prophylactically effective amount of a prophylactically effective *Helicobacter* polypeptide antigen by the sub-diaphragmatic, systemic route, wherein the route is "intraperitoneal" administration of a *Helicobacter* antigen, which induced protective immunity against *Helicobacter* infection (see page A681, col. 1, abstract 2, table and entire narrative). Chen et al anticipates the instantly claimed invention as now claimed.

21. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Fulginiti et al (1995). Fulginiti et al disclose the instantly claimed invention directed to a method that consists essentially of the step of :

22. Administering to a mammal a prophylactically effective amount of a prophylactically effective *Helicobacter* polypeptide antigen by the sub-diaphragmatic, systemic route, wherein the route is "intraperitoneal" administration of a *Helicobacter* antigen (see purified native urease

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admixed with cholera toxin, top half of abstract), wherein systemic serum antibodies were stimulated (see bottom half of abstract).

Fulginiti et al also discloses a method that consists essentially of:

Administering to a mammal a prophylactically effective amount of a prophylactically effective *Helicobacter* polypeptide antigen by the sub-diaphragmatic, systemic route, wherein the route is "intragastrically" administering a *Helicobacter* antigen (see *Helicobacter pylori* urease expressed in *Salmonella aroA* vaccine strain SL3261),.

Fulginiti et al anticipates the instantly claimed invention as now claimed.

23. Claims 5-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Michetti et al (US Pat. 6,290,962; filing date February 23, 1994) in light of evidence provided by Guy et al (1997)

Michetti et al claim a method of preventing *Helicobacter* infection (see col. 38, claims 71-72), the method comprising the step of :

administering a prophylactically effective amount of vaccine to a mammal (see Michetti et al, claims 21-22) that comprises *Helicobacter* urease together with *E.coli* labile toxin (see Michetti et al, claims 54, 69), wherein the mode of administering is by a subdiaphragmatic, systemic route, specifically by administering to a rectal surface (see Michetti et al, allowed claim 5, 25), and the *Helicobacter pylori* antigen being *Helicobacter* urease (see Michetti et al claim 42). An additional composition for administering to a patient contains a *Helicobacter pylori* antigen together with saponins (see Michetti et al allowed claim 29, and col. 12, lines 35 and 44), this composition inherently being one that would induce a Th-1 type immune response in

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light of evidence provided by Guy et al, page 148, that states saponin is a potent Th-1 inducer of immune responses).

Michetti et al inherently anticipates the instantly claimed invention as now claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
January 31, 2007


MARK NAVARRO
PRIMARY EXAMINER